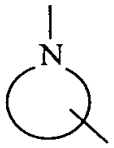
(Bd. Pat. App. & Inter. 1986), reviewing an Examiner's decision to reject claims under 35 U.S.C. § 112, first and second paragraph, for the alleged lack of enablement and indefiniteness of the terms "heterocycle" and "substituted" (id. at 1906-1907). In Breuer, the application in question disclosed how to make and use the claimed compounds, including 50 examples of the claimed compounds and a definition of both the terms "heterocycle" and "substituted" (id.). The U.S. Board of Patent Appeals reversed the Examiner's rejection based on the above facts in Ex parte Breuer and found sufficient disclosure to enable a person having ordinary skill to practice the claimed invention without undue experimentation (id. at 1907).

Like Breuer, the present specification provides a full definition of the term "heterocyclic" and/or derivatives of the term. Further, the present specification provides a full definition of the term"substituent" and/or derivatives of the term.

Specifically, at page 14, line 1 to page 29, line 12, the Applicants fully disclose the acceptable variants of the R^1 (including copious examples of suitable N-containing cycloalkyl groups), R^2, R^3, A^1, A^2, and A^3 substituents, as well as the heterocyclic substituent of formula:



for use in the present invention. Also like Breuer, the present specification discloses how to make the claimed compounds (page 4, line 21 to page 13, line 13 and at page 36, line 15 to page 47, line 24) and further provides nearly 250 examples of compounds having "heterocyclic" groups and "substituents" (see page 50, line 24 to page 165, line 11). In the Response to Applicant's Remarks, the Examiner states that "undue experimentation would be

required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor" (paper number 12, page 5, lines 12-15). In Breuer the Board did not find a patent including 50 examples of the claimed compounds to require undue experimentation or to have provided a "poor amount of direction." In view of the Board's holding, Applicants ask how the Examiner can hold an application that provides nearly 250 examples of the claimed compound not to be enabled? Therefore, as in Breuer, the Examiner's rejection should be withdrawn.

MPEP §2164.04 states:

> A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, *unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.*

Not only do the Applicants provide adequate disclosure to fully enable the skilled artisan to make the claimed compounds, the Examiner has not provided any reason whatsoever to "doubt the objective truth of the statements contained therein which must be relied on for enabling support." Accordingly, this rejection is also unsustainable since the Examiner has not met the burden necessary to refute the adequacy of the present disclosure.

Further regarding Claim 17, it appears that the Examiner has merely reasserted the rejection under 35 U.S.C. §112, first paragraph, *in toto*, without regard for breadth of the rejection. The Examiner has remained silent with respect to this ground of rejection and Applicants argument thereto. In Applicants response of June 12, 2002, Applicants pointed to page 1, line 21 to page 2, line 10, which sets forth that platelet aggregation and thrombus formation are widely recognized to be causative of a series of disorders including, restenosis

or reocclusion; the thrombus formation in case of vascular surgery, valve replacement, extracorporeal circulation or transplantation; disseminated intravascular coagulation; thrombotic thrombocytopenic; essential thrombocytosis; and inflammation.

As is clearly evident above, Applicants have adequately enabled the presently claimed compounds. In addition, Applicants provide adequate disclosure to fully enable the skilled artisan to use the presently claimed compounds (page 48, line 19 to page 50, line 1) and to enable the skilled artisan to assess the efficacy of the inventive compounds (page 47, line 31 to page 48, line 17).

Therefore, with the present specification in hand, the skilled artisan would require nothing more than *routine* skill to practice the invention as claimed in Claim 17 and to assess the efficacy of the presently claimed compounds.

In the Examiner's response to Applicant's Remarks, the Examiner states: "the applicant has only provided one working example of the invention which is example 21." However, there is no requirement for Applicants to provide working examples (see MPEP §2164.02). Again, the Examiner has not provided any reason whatsoever to "doubt the objective truth of the statements contained therein which must be relied on for enabling support" as required by MPEP §2164.04.

For all the foregoing reasons, Applicants request withdrawal of this ground of rejection.

Applicants submit that the present application is now in condition for allowance.

Early notification of such action is earnestly solicited.

Respectfully submitted,

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